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April 2, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane
Room 1061
Rockville, MD 20852

Re: BASF Corporation's Comments on FDA's Proposed Regulation on Registration of Food Facilities (Docket No. 02N-0276)

Dear Sir:

In response to the Food and Drug Administration's (FDA) notice of proposed rule making entitled "Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," BASF Corporation is respectfully submitting comments. The proposal, which was published in the Federal Register on February 3, 2003, (68 *Fed. Reg.* 5377) requests comments with regard to the registration of domestic and foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States.

Based in Mt. Olive, New Jersey, BASF Corporation (BC) is the North American affiliate of BASF Aktiengesellschaft, Ludwigshafen, Germany. BC's diverse product mix includes chemicals, coatings, plastic, colorants, and health and nutritional products. Many of these products, which are either manufactured here in the U.S. or imported[1] from our foreign affiliates, have applications in food as food additives. Given the proposal's definition of food as the meaning given in section 201(f) of the Federal Food Drug and Cosmetic Act, BC, as a manufacturer and supplier of both direct and indirect food additives, is subject to the proposed rule.

BASF supports Congress and the FDA in efforts to protect the U.S. food supply from threatened or actual terrorist attacks. Indeed, any and all contemplated measures designed to protect our society from an outbreak of food-borne illnesses are commended and taken seriously. As enacted by Congress the Bioterrorism Act requires facilities engaged in the manufacturing, processing, packing, or holding of "food for consumption" in the U.S. to register with the Secretary. BC believes that the term "food for consumption" as used by Congress, however, is not consistent with the definition of "food" in the proposal. We are concerned that the definition of food in the registration proposal is too broad, going beyond Congress's original intent to place safeguards on edible foods and their ingredients, and in doing so places an undue burden on business without a corresponding benefit to the security of the food supply.

02N-0276 C103

[1] The comments submitted here within are specifically related to the provisions of the registration proposal applicable to BC facilities that manufacture, process, pack or hold food for human or animal consumption in the United States. BC under separate cover will also be commenting on FDA's proposal for prior notice of the importation of food.

Request for Indirect Food Additive Exclusion from the Definition of Food

Within the true meaning of the words, "food for consumption" can only be interpreted as food that can be eaten in its present state, or edible food. BC supports the registration proposal for edible food including direct food additives insofar as they become intended ingredients of food for consumption. However, BC does not support the registration proposal for indirect food additives and is requesting that FDA exclude indirect food additives[2] in the proposal's definition of food. The primary function of an indirect food additive is associated with the manufacture of food contact articles, not as an ingredient of food for consumption. Although they are "components of immediate food packaging intended for food use", as described in the proposal's definition of food, BC does not believe it was the intent of Congress to extend the registration requirement to that length. The following comments are provided in support of our position.

At the 1/29/03 satellite public meeting to discuss the proposed regulation, an FDA official stated that the definition of a "manufacturer" means "anyone combining one or more food *ingredients.*" While the definition of a "manufacturer/processor" as proposed for 21 CFR 1.227(c)(6) includes additional language, i.e., "... or synthesizing, preparing, treating, modifying or manipulating food, including food crops or *ingredients*" the language proposed for that section reinforces that manufacturing/processing is making food from one or more ingredient and that the food that is made is "edible". Examples of manufacturing/processing that are included under the definition are clearly examples of edible food. Thus, it would appear FDA believed that Congress envisioned manufacturers of food for consumption (anyone combining one or more food ingredient) subject to the registration requirement. In addition, those synthesizing or preparing direct food additives would be subject to registration as direct food additives are intended *ingredients* of food for consumption. BASF believes the manufactures of indirect additives do not meet the proposed definition of a "manufacture/processor" as indirect additives are components of the packaging material that, due to migration, may become an unintentional component, not an intended ingredient, of the finished edible food.

As further support that Congress envisioned the registration of food facilities to extend to those facilities that manufacture, process, pack or hold food for consumption, including direct food additives, is the Bioterrorism Act's reference to the food categories as identified under 21 CFR 170.3. In the Bioterrorism Act, Congress instructed FDA that as part of the registration process they may require each facility to submit the general food category of any food manufactured, processed, packed or held by the facility. FDA's proposal includes, as mandatory fields of the registration form, categories from 21 CFR 170.3. The food categories stated in 21 CFR 170.3 are specific for food products and for direct human food ingredients that may be added to food products (direct food additives). 21 CFR 170.3 does not include categories for indirect food additives.

The inclusion of indirect food additives in the definition of food for purposes of the registration proposal will impose a tremendous burden on industry that is disproportionate to the risk associated with contaminating the U.S. food supply from that source. Indirect food additives are not likely to be the method of choice for use in a food-borne related terrorist attack. These substances are too far removed from the food chain in that they become unintended components of the finished food as a result of migration from the food-packaging article. If the components were contaminated with terroristic agents, biological or chemical, most would not survive the manufacturing processes employed during the production of the food-packaging article. For those

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[2] Within the context of the definition of food additives as given in 21 CFR 170.3 and the definition of food as found in the proposal, an indirect food additive for purposes of these comments are "components of immediate food packaging or food contact articles that migrate into food from the food packaging or the food contact article".

that may survive, migration from the finished package would have to occur in quantities that would have the desired effect. Thus, choosing this method to launch a terroristic attack poses obstacles that are countered productive to the overall success of any attempt.

BC would also like to note that chemical manufacturers are subject to a variety of initiatives designed to protect our country from terrorist attacks. Most notably are those initiatives under the American Chemical Counsel's Responsible Care Code #7-Security. These initiatives requires BC and other chemical companies to assess the threats and vulnerabilities associated with each product and institute security measures as appropriate. This type of a targeted assessment maximizes product security at reasonable costs. BC does not believe that requiring manufacturers, packers or holders of indirect food additives to register under the Bioterrorism Act will have the same affect and urges FDA to consider these other initiatives prior to issuing a final rule.

Request for Clarification With Regard to Threshold of Regulation for Substances Used in Food Contact Articles

While BC does not believe that Congress intended for the requirements of the Bioterrorism Act to extend to indirect food additives and believes that indirect food additives should be excluded from the definition of food for consumption, BC notes that the proposal as written is not clear on the extent to which components of immediate food packaging meet the definition of "food". Indirect food additives, as defined by current regulation, include any substance that may migrate into food as a result of the use of that substance in articles that contact food. This definition is consistent with the definition given in proposed 21 CFR 1.227(c)(4). Generally, the use of a substance as an indirect food additive extends to substances generally recognized as safe on food or in food packaging (21 CFR 182, 184, 186), used in accordance with prior sanction (21 CFR 181), and permitted for use by indirect food additive regulation (21 CFR 175, 176, 177, 178 and 179.45). However, the proposal does not address the use of substances that may migrate into food at negligible levels (below the threshold of regulation) and thus exempt from regulation as indirect food additives (21 CFR 170.39). Should FDA reject BC's request to exclude indirect food additives from the proposal's definition of food and the final rule requires manufacturers of these substances to register, BC is requesting that FDA clarify that substances that may migrate into food below threshold, thus exempt from regulation as indirect food additive per 21 CFR 170.39, will not be subject to the rule.

Request to Minimize Food Facility Registration Update Requirement

Proposed 21 CFR 1.234 requires that the owner, operator or agent in charge of a facility must submit updates to the registration within 30 calendar days of any change to any of the information previously submitted. While BC appreciates that FDA must act quickly when the need to respond to threatened or actual terrorist attacks arises, this update requirement is administratively difficult and places a continual regulatory burden on affected facilities. BC is requesting that FDA minimize this requirement by requiring the 30-day update for only that information deemed critical when responding to an emergency. Possible inclusions under this category are facility name/address information, facility emergency contact information, U.S. agent, human and animal product category, and owner, operator or agent in charge information. All other changes to the registration could be reviewed and updated as needed on a yearly basis. BC believes that this approach would minimize the burden on industry while still providing FDA with the information they need to respond to threatened or actual terrorist attacks.

Request For Clarification Concerning Information Required In The Food Facility Registration Form

BC is requesting that FDA clarify the meaning of "owner, operator or agent in charge " as related to the proposed registration procedures. Proposed 21 CFR 1.225 requires that the owner, operator, or agent in charge of a domestic or foreign facility must register the facility with FDA. Section 12 of the draft registration form restates this requirement. Although "owner, operator, or agent in charge" is referenced throughout the proposal and the draft registration form (section 1b and section 12), it has not been defined.

In addition, the draft registration form includes a box to be checked for owner, operator or agent in charge changes in section 1b, but it does not request specific information for the owner, operator or agent in charge elsewhere on the form. It is BC's assumption that FDA interprets the owner, operator or agent in charge of the facility *as the facility itself* (and not an individual) for which specific information is requested in section 2 of the form. Once the owner, operator or agent in charge of the facility has authorized an individual to submit the registration form, that individual becomes synonymous with the "owner, operator or agent in charge". BC is requesting that FDA confirm these assumptions or clarify alternate interpretation. If these assumptions were correct, BC would suggest that the last box under section 1b of the registration form be revised to "Authorized Submitter". Further, we believe that the second sentence of the certification form in section 12 should be revised as follows to improve clarity with respect to the authorization given by the owner, operator of agent in charge of the facility; "By submitting this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate and that the submitter has been authorized to register on its behalf".

Section 11 of the draft registration form requires information on general food categories. We note that FDA has stated on the form that warehouses are not required to complete this section. This exception is not mentioned in the preamble or in the proposed regulations. BC is therefore requesting that FDA clarify this exception before issuing the final rule.

Comment Concerning Confidential Business Information

BC commends FDA for the proposed provisions under 21 CFR 1.243 as some of the sensitive information provided in the registration form should clearly be protected from disclosure. However, at the public meeting to discuss the proposed regulation, an FDA official stated that it will share the information in the registration with other agencies, provided the other agencies give written assurance of confidentiality. BC is concerned that this written assurance will not ensure that the information obtained by other agencies will receive the same confidential treatment that would be given by FDA where it is specifically protected from public disclosures. We therefore urge FDA to ensure that the same level of CBI protection is required from other agencies if information from the registration form is shared.

BC is also concerned about the security of the registration information submitted electronically. Specifically, we would like the final rule to address the security measures that will be taken to protect the transmittal of information with regard to accuracy and access.

In summary, BC believes that requiring facilities that manufacturer, process or hold indirect food additives to register is contrary to the Bioterrorism Act's intent and places an undue burden on business without a corresponding benefit to the security of the food supply. We therefore are

requesting that FDA exclude these substances from the proposal's definition of food. We are also are requesting clarification with respect to the information asked for on the registration form and confidential business information. We appreciate the opportunity to comment on the proposed regulations and respectfully request that FDA take them into consideration before issuing a final rule.

Sincerely,

Claudia Skarbek Elias
Regulatory Manager